

Remarks

Status of Application

Claims 1-122 are pending in the present application, of which Claims 54-88 and 107-122 have been withdrawn and claims 27, 100, and 102 have been canceled, thereby leaving claims 1-26, 28-53, 89-99, 101, and 103-106 are at issue.

Summary of Pending Objections and Rejections

All of the claims at issue stand rejected. Amendment C has been objected to under 35 U.S.C. § 132(a), and all of the claims at issue stand rejected under 35 U.S.C. § 112 paragraphs 1 and 2, for the use of the word “solely” in presented amendments to the claims. All of the claims at issue also stand rejected as obvious over Carson et al. U.S. Patent No. 6,923,817 (hereinafter, “Carson”) in combination with Dance et al. U.S. Patent No. 5,611,353 (hereinafter “Dance”) and further in various combinations of Salehi et al. U.S. Patent No. 6,645,251 (hereinafter, “Salehi”), DiGioia (non patent literature) and Gustilo et al. U.S. Patent No. 6,162,257 (hereinafter, “Gustilo”). Furthermore, all of the claims at issue stand provisionally rejected for obviousness-type double patenting over claims 24-46 of copending Application No. 10/732,553 and over claims 21-35 of copending Application No. 11/148,520.

Explanation of Amendments and Support Therefor

Independent claims 1, 28, and 89 have been amended to remove the word “solely” and to recite additional clarifying features. Support for additional clarifying features recited in claims 1, 28, and 89 can be found at least at page 10, line 21-page 11, line 16 of the specification and FIG. 3.

Specific Responses to Pending Objections and Traversals of Pending Rejections

Applicants traverse the objection to Amendment C under 35 U.S.C. 132(a) and the rejections of claims 1-26, 28-53, 89-99, 101, and 103-106 under and 112, first and second paragraphs. Independent claims 1, 28, and 89 and claims 2-26, 29-53, 89-99, 101, and 103-106 dependent thereon, respectively, have been amended to remove the offending language. Therefore, these rejections should be withdrawn.

Applicants respectfully request the examiner to hold the provisional obviousness-type double patenting rejections in abeyance pending the indication of allowable subject matter in this or any one of the co-pending applications, at which time such rejections can be properly addressed as necessary.

In addition, the applicants traverse the rejections of claims 1-26, 28-53, 89-99, 101, and 103-106 as obvious over combinations of Carson and Dance and further in various combinations of Salehi, DiGioia, and Gustilo because the applied art does not disclose or suggest every recited claim element, as explained in detail herein-below. In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be disclosed or suggested by the prior art. MPEP § 2143.03 (citing *In re Royka*, 490 F.2d 981 (CCPA 1974)). Therefore, the pending obviousness rejections of the claims at issue should be withdrawn.

Summary of Independent Claims

Claim 1, as amended, and claims 2-26 dependent thereon, recite a method of performing a total arthroplasty of a ball and socket joint of a patient using a surgical navigation system, wherein the joint has a socket and a limb has a ball shaped head at a proximal end of the limb near the socket. The method includes the step of constructing a three dimensional model of the joint intra-operatively using an analysis of anatomical biomechanical axes of the joint and using the surgical navigation system to mark the patient's anatomical landmarks based on the marking of the patient's anatomical landmarks and the analysis of the anatomical biomechanical axes of the joint. Further, the method includes the step of preparing the limb to receive a stem using the three dimensional model, wherein the three dimensional model is sufficient for performing a virtual trial with implant information available in a database and virtually preparing the joint to receive an implant component. Still further, the method includes the steps of virtually assessing a proposed range of motion of the joint prior to inserting the stem in the limb, placing the stem in the limb, and verifying the proposed range of motion of the joint with a selected implant after placing the stem in the limb.

Claim 28, as amended, and claims 29-53 dependent thereon, specify a method of performing a total arthroplasty of a ball and socket joint of a patient using a surgical navigation system wherein the joint has a socket and a limb has a ball shaped head at a

proximal end of the limb near the socket. The method includes the step of constructing a three dimensional model of the joint intra-operatively using an analysis of anatomical biomechanical axes of the joint and the surgical navigation system to mark the patient's anatomical landmarks based on the marking of the patient's anatomical landmarks and the analysis of the anatomical biomechanical axes of the joint. The method further includes the step of performing a virtual trial of the joint and virtually preparing the joint to receive an implant component that provides optimum post surgery characteristics using the three dimensional model and implant component information stored in a database. In addition, the method includes the steps of preparing the limb to receive a stem using the three dimensional model, placing the stem in the limb, and determining the stability of the joint.

Claim 89, as amended, and claims 90-99, 101, and 103-106 dependent thereon, recite a method of performing a total arthroplasty of a ball and socket joint of a patient using a surgical navigation system wherein the joint has a socket and a limb has a ball shaped head at a proximal end of the limb near the socket. The method includes the step of constructing a three dimensional model of the joint intra-operatively using an analysis of anatomical biomechanical axes of the joint and the surgical navigation system to mark the patient's anatomical landmarks without using a scan. Further, the method includes the steps of providing a virtual trial of the joint using the three dimensional model of the joint and data relating to implant components chosen from a database of joint implant components, wherein the three dimensional model enables a surgeon to assess offset, leg length and a range of motion of the joint during the virtual trial with a proposed implant prior to commencing a surgical procedure. Furthermore, the method includes the steps of preparing a limb to receive a stem implant using the three dimensional model, and placing the stem implant within the prepared limb. The step of providing the virtual trial occurs before placing the stem implant within the prepared limb.

Rebuttals of Obviousness Rejections

None of the applied references discloses a method of performing total arthroplasty of a ball and socket joint, as recited in claims 1-26, including the steps of constructing a three dimensional model that is sufficient for performing a virtual trial with implant information available in a database and virtually preparing the joint to receive an implant component, or the steps of virtually assessing a proposed range of motion of the joint prior to inserting the

stem in the limb and verifying the proposed range of motion of the joint with a selected implant after placing the stem in the limb.

Further, none of the cited references disclose or suggest a method of performing total arthroplasty of a ball and socket joint, as recited by claims 28-53, including the step of constructing a three dimensional model of the joint intra-operatively using an analysis of anatomical biomechanical axes of the joint and the surgical navigation system to mark the patient's anatomical landmarks based on the marking of the patient's anatomical landmarks and the analysis of the anatomical biomechanical axes of the joint, and the step of performing a virtual trial of the joint and virtually preparing the joint to receive an implant component that provides optimum post surgery characteristics using the three dimensional model and implant component information stored in a database.

Furthermore, none of the cited art discloses or suggests a method of performing a total arthroplasty of a ball and socket joint, as recited in claims 89-99, 101, and 103-106, including the steps of constructing a three dimensional model of the joint intra-operatively and providing a virtual trial of the joint using the three dimensional model of the joint and data relating to implant components chosen from a database of joint implant components, wherein the three dimensional model enables a surgeon to assess offset, leg length and a range of motion of the joint during the virtual trial with a proposed implant prior to commencing a surgical procedure, and wherein the step of providing the virtual trial occurs before placing the stem implant within the prepared limb.

In fact, Carson discloses a total knee arthroplasty system and process wherein fiducial markers are placed on a patient's body part such as a femur or tibia and a fluoroscopic image of the femur or tibia is taken. The image is registered with the body part so that a navigation system can track the body and enable a surgeon to look at a computer screen and see the position and orientation of the body part during a surgical procedure. The image is also used to designate anatomical landmarks on the patient so that the surgeon can determine various mechanical and rotational axes of the femur or tibia that may be necessary for assessing progress of the surgical procedure. The surgeon can then resect the femur or tibia and modify the bone as necessary. Next, however, the surgeon must iteratively perform trial installations to determine which implant of a number of different implants is suitable for that patient by physically inserting different trial implants into the patient's body and assessing the fit of the implant by using the navigation system. Only during the trial installation is the surgeon able

to view and analyze the relative motion of the relevant body part and make soft tissue releases to improve the kinematics of the body part if necessary.

Thus, Carson does not disclose or even suggest obtaining a three-dimensional model that is either capable of being, or actually is used for performing a virtual trial of a joint with the three-dimensional model and implant information so that an optimum range of motion can be considered before ever placing a physical implant of any kind into the already resected bones of the patient. Rather, Carson teaches a “trial and error” method of determining a suitable implant using actual implants during a surgical procedure. (*See Carson at column 16, line 43-column 17, line 30*). Further, the disclosures of Salehi, Dance, DiGioia, and Gustillo do not supply the above-identified deficiencies in Carson.

Rather, Salehi discloses an implant component having surfaces that include indentations or patterns machined therein to reduce the contact area of an articulating implant component, thereby reducing wear on the component.

Dance discloses a method and apparatus for determining the weight bearing axis from the center of the hip joint to the center of the ankle joint during knee surgery to ensure proper placement of implant components relative to a patient’s anatomy.

DiGioia discloses an image guided navigation system (HipNav) to intraoperatively measure acetabular implant alignment to prevent malposition of components during a total hip replacement.

Gustilo discloses an acetabular cup prosthesis that is designed to customize the fit and stability of an acetabular cup that is deficient in acetabulae while reducing the reaming of good bone around the deficiency.

A surgical procedure that utilizes the method disclosed by Carson in combination with any of the other cited art requires an extra step of physically inserting trial implants in a patient during the surgical procedure. In contrast, an advantage of the methods, systems, and apparatus disclosed herein is the elimination of any requirement for such trial insertions. Specifically, the methods the methods, systems, and apparatus disclosed herein enable a surgeon to predetermine the best implant and implant position for a patient prior to inserting any implants into the patient’s body, thereby saving time during the surgery and minimizing invasion of the patient’s body.

Because the cited references do not disclose or suggest all of the recited elements of the claims, either alone or in combination, it follows that the claims are not anticipated by or

obvious thereover and the obviousness rejections thereover should be withdrawn, notice of which is respectfully requested.

Conclusion

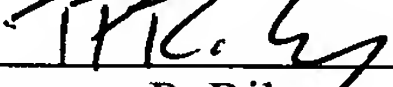
For the foregoing reasons, reconsideration and allowance of the claims at issue are respectfully respected.

The examiner is invited to call the undersigned attorney at the telephone number indicated below to discuss the pending claims or the remarks presented herein, if the examiner believes that such conversation would be helpful for the purpose of expediting this prosecution.

Respectfully submitted,

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